



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-day comment request

The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on March 25, 2014 (Vol. 79, No. 57, pages 16345-16347). Three comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact either: Dr. Larissa Aviles-Santa, 6701 Rockledge, Epidemiology Branch, Program in Prevention and Population Sciences, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr, MSC 7936, Bethesda, MD 20892-7936, or call non-toll-free number 301-435-0450, or E-mail your request, including your address to avilessantal@nhlbi.nih.gov . Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Hispanic Community Health Study/ Study of Latinos (HCHS/SOL), Revision, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to study the prevalence of cardiovascular and pulmonary disease and other chronic diseases, and their risk and protective factors, understand their relationship to all-cause, cardiovascular and pulmonary morbidity and mortality, and understand the role of sociocultural factors (including acculturation) on the prevalence or onset of disease among over 16,400 Hispanics/Latinos of diverse origins, aged 18-74

years at enrollment, living in four U.S. communities: San Diego, California; Chicago, Illinois; Miami, Florida, and the Bronx, New York. In order to achieve these objectives, the HCHS/SOL had two integrated components:

1. Examination of the cohort following a standardized protocol, which consisted of interviews and clinical measurements to assess physiological and biochemical measurements including DNA/RNA extraction for ancillary genetic research studies.

2. Follow-up of the cohort, which consists of an annual telephone interview to assess vital status, changes in health status and medication intake, and new cardiovascular and pulmonary events (including fatal and non-fatal myocardial infarction and heart failure; fatal and non-fatal stroke; and exacerbation of asthma and chronic obstructive pulmonary disease). This component also includes contact with physicians and informants to obtain medical information about participants.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 75,305.

Estimated Annualized Burden Hours

A.12.1 ESTIMATES OF HOUR BURDEN (APPENDICES 11, 14 AND 15)					
Type of Respondents	Survey Instrument	Number of Respondents	Number of Responses Per Respondent	Average Time per Response (in hours)	Total Burden Hours
Participants Visit 2 Examination (Appendices 11 and 14)	Pre-visit scheduling & safety screening (Appendix 14 -Procedures-ELE bilingual)	13878	1	2/60	463
	Reception, informed consent (Appendix 11), medical releases	13878	1	20/60	4626
	Ppt. disability screening	13878	1	4/60	925
	Ppt. safety update and routing (Appendix 14 -Procedures-PSE bilingual)	13878	1	2/60	463
	Change clothes, urine specimen (Appendix 14-Procedures-BIO)*	13878	1	10/60	2313
	Updated personal information	13878	1	5/60	1157
	Anthropometry	13878	1	7/60	1619

	Determination of fasting & blood draw (Appendix 14-Procedures-BIO)*	13878	1	11/60	2544
	Determination of blood glucose, OGTT (Appendix 14-Procedures-BIO)*	13878	1	6/60	1388
	Seated BP	13878	1	9/60	2082
	Echocardiography	8000	1	30/60	4000
	2-hour blood draw, snack (Appendix 14-Procedures-BIO)*	13878	1	12/60	2776
	Personal Medical History	13878	1	10/60	2313
	Reproductive Medical History	9000	1	9/60	1350
	Pregnancy Complications History	9000	1	6/60	900
	Socio-economic Status – Occupation	13878	1	3/60	694
	Health Care Access and Utilization	13878	1	15/60	3470
	Chronic Stress	13878	1	4/60	925
	Family Cohesion	13878	1	5/60	1157
	Social Support	13878	1	3/60	694
	Acculturation	13878	1	3/60	694
	Well Being	13878	1	4/60	925
	Abbreviated Medication Use	13878	1	4/60	925
	Tobacco Use	13878	1	7/60	1619
	Alcohol Use	13878	1	3/60	694
	Participant Feedback	13878	1	12/60	2776
	Total			206/60	43492
Participants AFU Phone Interview (Appendix 15)	AFU Year 3	3146	1	15/60	787
	AFU Year 4	9033	1	15/60	2258
	AFU Year 5	14259	1	15/60	3565
	AFU Year 6	16222	1	15/60	4055
	AFU Year 7	16222	1	15/60	4055
	AFU Year 8	16222	1	15/60	4055
	AFU Year 9	16222	1	15/60	4055
	AFU Year 10	16222	1	15/60	4055
	AFU Year 11	16222	1	15/60	4055
	Total			120/60	30940
Physicians and/or other health care providers	Hospitalization records/ physician interview (Appendix 16, PQE)	1591	1	30/60	796
Informants	Informant Interview Deaths (Appendix 16, IIE/IIS)	154	1	30/60	77
	Total			60/60	873

Dated: June 18, 2014.

Michael Lauer,
Director,
DCVS, NHLBI, NIH.

Dated: June 18, 2014.

Lynn Susulske,
NHLBI Project Clearance Liaison,
National Institutes of Health.

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